Applicant: Steve Golden Serial No.: 10/715,797 Filed: November 18, 2003

Docket No.: P0021729.02 / M190.321.101

Title: APPARATUS AND METHODS FOR ANASTOMOSIS

REMARKS

This is responsive to the Non-Final Office Action mailed May 21, 2008. In that Office Action, claims 64, 123-125, and 127-131 were rejected under 35 U.S.C. §102(e) as being anticipated by LaFontaine et al., U.S. Patent No. 6,443,158 ("LaFontaine"). Claims 66-74, 126, 132, 135-137, and 139-141 were rejected under 35 U.S.C. §102(e) as being anticipated by LeMole, U.S. Patent No. 5,893,369 ("LeMole"). Claim 75 was rejected under 35 U.S.C. §103(a)s being unpatentable over LeMole in view of Ho et al., U.S. Patent No. 6,514,265 ("Ho").

The Examiner's indication that claims 76-81 have been allowed and that claims 133, 134, and 138 are allowable is noted with appreciation.

With this Response, claims 64, 66, 76, 123, 127, and 128 have been amended. The amendment to claim 76 corrects an unintentional typographical concern introduced in the previous Amendment and Response. Claims 64, 66-81, and 123-141 remain pending in the application and are presented for reconsideration and allowance.

35 U.S.C. §§102, 103 Rejections

LaFontaine Rejections

LaFontaine relates to a system and method for percutaneous coronary artery bypass through a venous vessel. Initially, and as shown in FIG. 3, proximal and distal ends of a restriction 22 in a coronary artery 16 are located. An elongate portion or tubular member 58 of a cutting device 56 is inserted into the artery 16 (FIG. 5A); steered outwardly through a wall of the artery 16 and into a vein 20 (FIG. 5B); and then steered outwardly through the wall of the vein 20, through a wall of the artery 16, and back into the artery 16 (FIG. 5D). Subsequently, the tubular member 58 is removed, leaving only a guide wire 66 as shown in FIG. 5E. An introducer 88/90 carrying a graft 86 is then fed over the guide wire 66 and along the previously cut path through and between the artery 16 and the vein 20, resulting in the arrangement of FIG. 6C. Ends of the graft 86 are then secured to an interior of the artery 16 via stents 94, 96. With this

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understanding of LaFontaine in mind, it is respectfully submitted that the rejections of independent claims 64, 123, 127, and 128 based on LaFontaine should be withdrawn.

With respect to independent claim 64, claim 64 recites positioning a cannula through a vessel wall and attaching a graft to the vessel wall adjacent the cannula. In rejecting claim 64, the Office Action identifies the <u>tubular member 58</u> of LaFontaine as being the claimed "cannula". While the tubular member 58 may or may not constitute a cannula, LaFontaine clearly describes that the tubular member 58 is entirely removed <u>prior to</u> deploying and attachment of the graft 86. For example, as shown in FIG. 5E of LaFontaine, the tubular member 58 (FIGS. 5A and 5B) has been removed. Thus, use of the tubular member 58 in accordance with the disclosure of LaFontaine does not teach positioning the cannula 58 <u>and</u> attaching a graft adjacent to the cannula 58 while the cannula 58 extends through the vessel wall.

In addition, claim 64 has been amended to recite that a piercing end of the cannula pierces through the vessel wall, and that the graft is attached to the vessel wall adjacent the piercing end. As described above, use of the tubular member 58 of LaFontaine does not teach these features. Further, the introducer 88/90 does not have a piercing end, and deployment of the introducer 88/90 does not include piercing through vessel wall. Instead, any "piercing" accomplished with the methodology of LaFontaine is provided solely through use of the cutting device 56/tubular member 58. Thus, the disclosure of LaFontaine relative to use of the introducer 88/90 does not teach every feature of claim 64. For at least these reasons, then, it is respectfully submitted that the rejection of claim 64, as well as claims 124 and 125 depending therefrom, should be withdrawn.

With respect to independent claim 123, the Office Action's reference to use of the tubular member 58 does not teach the "attaching a graft to the vessel wall adjacent to said cannula while said cannula extends through said vessel wall" features of claim 123 as described above with respect to claim 64. In addition, claim 123 has been amended to recite that the cannula is passed through another portion of the vessel wall into the interior of the vessel, and then from the interior vessel through the vessel wall. LaFontaine discloses an opposite methodology. In particular, LaFontaine describes the introducer 88/90 passing from the interior of the vessel 16

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and through the vessel wall (i.e., FIG. 6B), followed by passage of the introducer 88/90 from the exterior of the vessel 16, through the vessel wall, and into the vessel interior (FIG. 6C). In other words, amended claim 123 recites passing the cannula through the vessel wall and into an interior of the vessel, followed by extension through the vessel wall from the interior (e.g., exterior to interior passage, followed by interior to exterior extension); in contrast, LaFontaine teaches interior to exterior passage, followed by exterior to interior extension. For at least these reasons, then, it is respectfully submitted that amended claim 123 is allowable over LaFontaine.

Independent claim 127 recites passing a first end of a tubular member from an interior of a vessel through a wall of the vessel at a first vessel wall location. As amended, claim 127 further recites that a graft is attached to the first vessel wall location adjacent the first end of the tubular member. As described above, the tubular member 58 of LaFontaine is removed prior to attachment of the graft 86, and thus use of the tubular member 58 cannot teach the "attachment" features of claim 127. Further, FIG. 6C illustrates the stent 94 associated with the graft 86 as being spaced from the vessel wall location at which the introducer 88/90 passes through the vessel 16 wall. The stent 94 defines the location at which the graft 86 is attached to the vessel 16. In light of the discrete arrangement of the stent 94 relative to the vessel wall location at which the introducer 88/90 passes through, the methodology of LaFontaine does not teach "attaching a graft to the first vessel wall location" of claim 127. For at least these reasons, independent claim 127, as well as claims 129-131 depending therefrom, are allowable over LaFontaine.

Independent claim 128 recites that a tubular member is initially passed through a vessel wall at a second location to deliver a first end of the tubular member into an interior of the vessel before passing the first end of the tubular member from the interior through the vessel wall at a first vessel wall location. LaFontaine is in direct opposition. More particularly, LaFontaine passes the tubular member 58 (as well as the introducer 88/90) from an interior to an exterior of the vessel 16, followed by passage from the exterior to the interior. In other words, claim 128 recites exterior to interior passage, followed by interior to exterior passage; LaFontaine discloses interior to exterior passage, followed by exterior to interior passage. In addition, claim 128 has

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been amended to recite attaching a graft to an exterior of the vessel wall. In contrast, FIG. 6E of LaFontaine teaches attachment of the graft 86 to the <u>interior</u> of the vessel 16 wall. For at least these reasons, it is respectfully submitted that claim 128 is allowable over LaFontaine.

LeMole Rejections

With respect to the rejections based on LeMole, Applicant incorporates by reference all previous arguments.

In addition, with respect to independent claim 66, claim 66 has been amended to recite that a graft is <u>connected</u> to a vessel at an opening formed in the vessel <u>after</u> the step of forming the opening and removing a portion of the vessel wall. In contrast, FIGS. 5 and 6 of LeMole clearly show that the graft 14 is connected to the vessel 12 <u>prior</u> to formation of an opening in the vessel wall (and/or removing a portion of the wall where the opening was formed). FIGS. 7 and 8, further illustrate that the opening in the vessel 12 wall is formed (and a wall portion removed) subsequent to connection of the graft 14. For at least these reasons, then, it is respectfully submitted that amended claim 66, as well as claims 67-74, 126, 132, 135-137, and 139-141 depending therefrom, are allowable over LeMole.

CONCLUSION

In view of the above, Applicant respectfully submits that pending claims 64, 66-81, and 123-141 are in form for allowance and are not taught or suggested by the cited references. Therefore, reconsideration and withdrawal of the rejections and allowance of claims 64, 66-81, and 123-141 are respectfully requested.

No fees are required under 37 C.F.R. 1.16(b)(c). However, if such fees are required, the Patent Office is hereby authorized to charge Deposit Account No. 50-0471.

The Examiner is invited to contact the Applicant's representative at the below-listed telephone numbers to facilitate prosecution of this application.

Any inquiry regarding this Amendment and Response should be directed to either Katrina Witschen at Telephone No. (763) 505-8418, Facsimile No. (763) 505-8436 or Timothy A. Czaja

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at Telephone No. (612) 573-2004, Facsimile No. (612) 573-2005. In addition, all correspondence should continue to be directed to the following address:

Medtronic CardioVascular

HUST 21,7008

7000 Central Avenue Minneapolis, MN 55432

Respectfully submitted,

Steve Golden,

By their attorneys,

DICKE, BILLIG & CZAJA, PLLC Fifth Street Towers, Suite 2250 100 South Fifth Street Minneapolis, MN 55402

Telephone: (612) 573-2004 Facs/mile: (612) 573-2005

Гіmothy A. Сzаја

Reg. N/o. 39,6/49